# BEST AVAILABLE CC.

Docket No. 01662/54802 Serial No. 09/916,885

#### **REMARKS**

Claims 62-64 have been added by the present amendment and therefore claims 1-64 are pending. Claims 21-61 have been withdrawn from consideration. Claim 1 has been amended to recite oxidizing 2-[(diphenylmethyl)thio]acetamide in a mixture comprising H<sub>2</sub>O<sub>2</sub>, a mineral acid, and either an alcohol or phase transfer catalyst, to more accurately recite the present invention. Claims 1-10 and 13-20 stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious by U.S. Patent No. 4,177,290 to Lafon ("Lafon"). Applicants respectfully traverse this rejection as a *prima facie* case of obviousness has not been raised.

As the Examiner is well aware, in order to establish a *prima facie* case of obviousness, three basic criteria must be met: 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings; 2) there must be a reasonable expectation of success; and 3) the prior art reference or references must teach or suggest all the claim limitations. Applicants submit that there is no motivation in the art to modify Lafon to produce the claimed invention and that Lafon does not teach or suggest all the limitations of the present claims.

Lafon describes preparing modafinil by oxidizing 2[(diphenylmethyl)thio]acetic acid with hydrogen peroxide in acetic acid. There is no teaching or suggestion anywhere in Lafon to oxidize 2-

[(diphenylmethyl)thio]acetamide to modafinil in a mixture comprising  $H_2O_2$ , a mineral acid, and either an alcohol or a phase transfer catalyst as recited in the present claims. The Office Action states that "it would have been obvious to one of ordinary skill in the art to determine through routine experimentations the optimum, operable acid to be used in the solution in the Lafon reference in order to crystallize a product with less impurities in the solid form." However, the Office Action points to no teaching or suggestion in Lafon that the choice of acid is a result-effective variable. Therefore, there is no motivation or suggestion to substitute mineral acid for acetic

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acid in Lafon's oxidation step. Moreover, with respect to claims 62 and 63, which recite a catalytic amount of mineral acid, Lafon teaches using an excess amount of

acetic acid (60 ml) and there is no teaching or suggestion in Lafon to substitute the catalytic amount of mineral acid for the excess amount of acetic acid used by Lafon.

Furthermore, Lafon does not teach or suggest using an alcohol or phase transfer catalyst in the oxidation step. The Examiner states that diphenylmethylthioacetamide is placed in a container and hydrogen peroxide, an acid and alcohol are added to the container. Applicants, however, are unable to find such a description of an alcohol in Lafon and respectfully request clarification. On the contrary, as described in Example 1a(b) of Lafon, hydrogen peroxide is passed over the reaction mixture and acidification is carried out with hydrochloric acid to obtain benzyhydrylsulphinylacetic acid without use of any alcohol. There is also no teaching or suggestion of using either an alcohol or phase transfer catalyst in this oxidation step. In Example 1 of Lafon, methanol is used in the crystallization step and not the oxidization step. Applicants believe that the rejection of the claims for obviousness—which is to be based upon the state of the art as of the date of invention—has, instead, been based upon hindsight gleaned from Applicants' own disclosure. Applicants therefore submit that claims 1-10, 13-20, and 62-64 are not rendered obvious by Lafon.

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### **CONCLUSION**

The Examiner is invited to contact the undersigned at (202) 220-4265 to discuss any matter concerning this application. The Office is authorized to charge any fees related to this communication to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,

Dated: 12-19-33

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